Research Administrators' Network Meeting

AGENDA

February 22, 2018
2:00-4:00 p.m.
Michigan League Ballroom
Webcast - http://orsp.umich.edu/ran-meeting-live-stream

Welcome & Introductions [2:00-2:10]

Becky O'Brien, RAAC Communications Subcommittee Chair
Kathy DeWitt, Guest Emcee

Updates [2:10-2:40]

Sponsored Programs - Bryan VanSickle, Financial Sr Manager, Sponsored Programs [2:10-2:20]
Office of Research & Sponsored Projects - Craig Reynolds, Executive Director, ORSP [2:20-2:30]
ITS - Cathy Handyside, Assistant Director, eResearch Administration Systems [2:30-2:40]

Intro To Offices: [2:40-3:00]

Human Subject Incentives Program - Alex Yribar, Program Manager
Office of Technology Transfer - Bryce Pilz, Director of Licensing
Small Business Plans - Amanda Hoeft, Procurement Solutions Administrator and Lynda Lyall, Procurement Solutions Manager

Networking: Meet the Office Representatives [3:00-3:25]

Meet with representatives from the offices above at assigned tables

Featured Presentation: [3:25-3:45]

IRB Review at U-M: What Research Administrators Need to Know
Ray-Nitra Reynolds, Education Coordinator, IRBMED
Cindy Shindledecker, IRB-HSBS Director

Professional Development Spotlight [3:45-3:55]

Announcements - Professional Societies and Navigate Updates
ORSP/Sponsored Programs - David Mulder, Training Manager

Closing Remarks [3:55-4:00]

RAN schedule for the rest of this Academic Year:
http://orsp.umich.edu/ran

Ideas for a future meeting?
Contact ran-plans@umich.edu

Brought to you by the Research Administration Advisory Council (RAAC) Communications Subcommittee.

Research Administrators' Network

Welcome!

February 22, 2018

Sponsored Programs Update

Research Administrators' Network

Bryan VanSickle, Financial Senior Manager, Finance-Sponsored Programs
February 22, 2018

Single Audit

Uniform Guidance Single Audit

- Still working on FY17 audit
- FY18 audit work begins April 2018

Property Disposition

Asset Management

- Track movement of property purchased for a project.
- When the property acquired for a project is no longer needed, follow SPG 520.01 - Acquisition, Use and Disposition of Property (Exclusive of Real Property) - http://spg.umich.edu/policy/520.01

Staff updates

Customer Service

- New coordinators effective February 1

Reporting

- Aaron Campbell promoted to Operations Manager

- Scott Culver promoted to Accounting Supervisor

- Four new accountants and two new interns started January

ORSP Update

Research Administrators' Network

Craig Reynolds, Executive Director, ORSP
February 22, 2018

Staff Updates

New Assistant Project Representatives

- **Caitlin Jost,** Private Sponsors Team

- **Daniela Marchelletta,** Government Sponsors Team

- **Reynaldo Martell,** Government Sponsors Team

Policies and Procedures Updates

- **Internal Deadline Policy**
  - 4-day and 2-day levels of service
  - Cross-campus working groups defining eRPM requirements and implementation details
  - Soft launch September 1, 2018
  - Hard launch July 1, 2019

- **Post-Award Change Request (PAC-R) Form Updated**
  - Signature line now has typed-name option

Policies and Procedures Updates

- **Agreement Acceptance Requests Reminder**
  - Step-by-Step Procedure: www.umich.edu/~eresinfo/erpm/docs/PM_PT_AgreementAcceptance.pdf
  - A different eResearch project type (*i.e.*, not a PAF)
  - Reminder via:
    - email notice
    - PAF
    - eRPM home workspace beneath “PAFs with Required Action” listing
  - Different approvals required depending on AAR type
  - Sometimes stops with Project Team for editing prior to routing to Principal Investigator (PI) for approval

eResearch Award Management System

- **Award Management Tracks**
  - Initial Award Set Up
  - Compliance
  - Award Modifications
  - Data Conversion
  - Reporting
- **Timeline**
  - Testing and User Acceptance - June 2018
  - Training - July 2018
  - Go live - August 2018

Federal Update - Common Rule Delay

- Revised *Federal Policy for the Protection of Human Subjects* delayed until July 19.
- eResearch and IRB process changes on hold until July 19.
- Self-determination review of certain exempt projects not available until July 19.
- Continuing review still required (for now) for qualifying minimal-risk research.
- For studies under IRBMED oversight, continue using IRBMED-approved templates.
- For studies under IRB-HSBS oversight, OK to use consent documents now that meet the 2018 Common Rule requirements.

Federal Update - NIH

Clinical Trials Transformation Reminders

- Video on ORSP's YouTube Channel - http://myumi.ch/JDo9n
- NIH Definition of a Clinical Trial is:
  - *...a research study in which one one more human subjects are prospectively assigned to one or more interventions...to evaluate effects of those interventions on health-related biomedical or health-related behavioral outcomes.*
- Good Clinical Practice (GCP) training
- Specific FOAs and review criteria
- FORMS-E and PHS Human Subjects and Clinical Trials Information Form
- Single IRB for multi-site studies
- Registration and reporting in clinicaltrials.gov

Federal Update - NIH

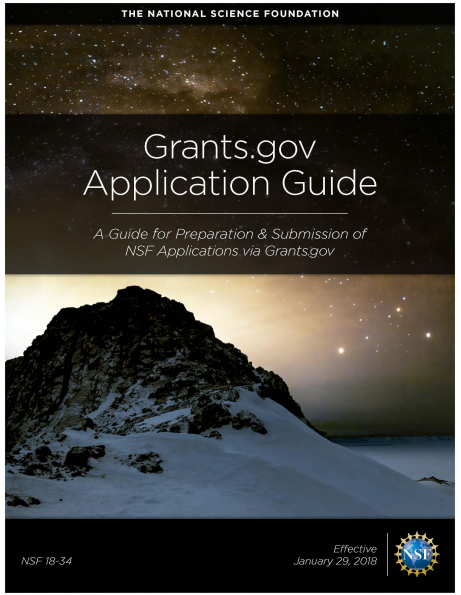
- **Inclusion Across the Lifespan Policy**
  - See NOT-OD-18-116
  - Effective with application due dates on or after January 25, 2019
  - Studies involving human subjects must have a plan describing how participants across the lifespan will be included and justify the proposed age range of participants.

Federal Update - NSF

New PAPPG

- https://www.nsf.gov/publications/pub_summ.jsp?ods_key=papp

- **Significant Changes:**
  - Collaborators & Other Affiliations (COA) Information provided through use of COA template.
  - Project Description must now contain separate section identified as “Intellectual Merit.”
  - Budget Justification increased to no more than five pages.



ITS Update

Research Administrators' Network

Cathy Handyside, Assistant Director of eResearch Administration Systems
February 22, 2018

NIH FORMS-E

- NIH FORMS-E
  - New forms introduced by NIH for proposals due on and after Jan. 25, 2018
- New Human Subjects & Clinical Trials Form
  - Issues encountered with use of this form
    - Some required ITS intervention prior to submission
  - eRPM - Vendor Fixes
    - Fix implemented Feb. 7, 2018
    - Additional fix scheduled for Feb. 26, 2018

NIH FORMS-E

Known issues addressed Feb. 7, 2018:

- Study Title on the Study Record errors if title is greater than 30 characters.
- Not Applicable (N/A) option for No Minimum or Maximum Age is not working on the Study Record, in Section 2. Population Characteristics, Item 3. Age Limits.
- Display order for the study records and delayed onset studies not respected.

NIH FORMS-E

Known issues to be addressed Feb. 26, 2018:

- The Cumulative (Actuals) Enrollment table on a study record not calculating correctly.
  - If you have a submission prior to Feb. 26, ITS Action Required prior to submission.
- A few text boxes are truncated on the Generated PDF.
- Document uploaded not appearing in the Generated PDF.

Intro to Offices: Human Subject Incentives Program (HSIP)

Research Administrators' Network

Alex Yribar, Program Manager
February 22, 2018

Human Subject Incentives Program (HSIP)

Who we are:

The HSIP is a team of three, led by **Alex Yribar**, HSIP Manager.

What we do:

HSIP works closely with research study teams across U-M to facilitate the disbursement and documentation of incentive payments to research study participants.

Human Subject Incentives Program (HSIP)

How we relate to the research administration enterprise:

We work with study teams to inform them about the HSIP process, and help answer inquiries that arise from study participants. We also work with the IRBs in part to help ensure teams are collecting the necessary payment data from their participants.

Some of the common issues / pitfalls we see:

The most common issues we encounter revolve around the receipt documentation we obtain from study teams. These range from illegible documents provided to critical information not provided to our office.

Human Subject Incentives Program (HSIP)

How research administrators can contact us:

subject-incentives@umich.edu

http://www.finance.umich.edu/treasury/hsip

Look for the HSIP table to speak with Alex

during the Networking portion of the meeting!

Intro to Offices: Office of Technology Transfer (OTT)

Research Administrators' Network

Bryce Pilz, Director of Licensing
February 22, 2018

Office of Technology Transfer (OTT)

Who we are:

The OTT Licensing team is comprised of 15 individuals, led by **Bryce Pilz**, Director of Licensing.

What we do:

OTT handles patent filings for faculty inventions, marketing of those technologies to industry, licensing U-M intellectual property to industry, and handles all incoming and outgoing material transfer agreements.

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Office of Technology Transfer (OTT)

How we relate to the research administration enterprise:

We license intellectual property rights in inventions that are created during the course of U-M's research partnerships. For these inventions, we need to:

1. Report to federal agencies to comply with the Bayh-Dole Act; and
2. Ensure that our handling of the invention is consistent with any prior industry and/or foundation research funding.

Some of the common issues / pitfalls we see:

- Figuring out who handles agreements that are in between the cracks of ORSP/Procurement/others, and often have time-sensitive responses
- Complying with the underlying funding agreements that relate to inventions reported to our office

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Office of Technology Transfer (OTT)

How research administrators can contact us:

techtransfer@umich.edu or (734) 763-0614

https://techtransfer.umich.edu/

Look for the OTT table to speak with Bryce during the Networking portion of the meeting!

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Intro to Offices: Procurement Services – Small Business Plans (SBP)

Research Administrators' Network

Amanda Hoeft, Procurement Solutions Administrator
Lynda Lyall, Procurement Solutions Manager
February 22, 2018

Small Business Plans (SBP)

Who we are:

The Procurement Solutions team is comprised of four individuals, who help administer small business plans, among other responsibilities.

What we do:

The Procurement Solutions team assists research administrators and principal investigators in creating small business plans, when the parameters of the federal contract or subcontract require a small business plan.

Small Business Plans (SBP)

How we relate to the research administration enterprise:

By assisting with the creation of SBPs, we help ensure that small business subcontracting goals are met. Failure to meet the subcontracting goals may negatively affect future funding prospects for other U-M applicants.

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Small Business Plans (SBP)

Some of the common issues / pitfalls we see:

1. We ask for two weeks notice to create the plan, however we receive many requests that need to be done within 48 hours or less.

2. We are unaware of changes to the contract that would affect federal reporting.

3. During federal reporting (April/Oct), the sponsor requires us to provide a comment as to why SBP goals are not being met and the plan to make good faith effort–we need the department to provide this explanation.

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Small Business Plans (SBP)

How research administrators can contact us:

research_liaison@umich.edu or (734) 764-8212, prompt 2

http://procurement.umich.edu/diversity-sustainability/small-business-subcontracting

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Look for the SBP table to speak with Amanda or Lynda during the Networking portion of the meeting!

IRB Review at U-M - What Research Administrators Need to Know

Research Administrators' Network

Ray-Nitra Reynolds, Education Coordinator, IRBMED
Cindy Shindledecker, Director, IRB-HSBS
February 22, 2018

Session Topics

- Overview of IRBs
- Requirements for IRB Approval
- Issues with timely IRB Approval
- Timing for an Award and IRB Approval
- Single IRB-of-Record Requirements
- Certificates of Confidentiality
- Where to get more information

What is an IRB?

- An Institutional Review Board is an **independent** review board that is responsible for **protecting the rights and welfare of human subjects participating in research** by ensuring that the research is conducted:
  - In accordance with **ethical** principles
  - In compliance with federal **regulations,** other federal, state and local laws, and institutional policies
- U-M IRBs are also responsible for supporting the research mission of the University.

IRBs at Michigan

1. **IRBMED (5 boards)**
    - Research conducted by faculty/staff/trainees of Michigan Medicine
    - Using Michigan Medicine facilities and patients (including their records)
    - Research regulated by the FDA (drugs/biologics/medical devices)
    - Research from other units that is physically invasive or may pose a physical risk (e.g. muscle biopsies, fMRI, etc.)

IRBs at Michigan

2. **IRB-HSBS (2 boards)**
    - Research conducted by Ann Arbor campus units that does not require IRBMED oversight
    - IRB-HSBS reviews some exempt projects from IRBMED units
3. **IRB-Dearborn**
    - Research conducted by Dearborn campus units, except where special expertise required (e.g. FDA-regulated or prisoners)
4. **IRB-Flint**
    - Research conducted by Flint campus units (as above)

The IRB vs. the IRB Office

The IRBs

- Each **IRB is made up of at least 5 members** with expertise to review the research under its jurisdiction
  - Primarily made up of faculty members, but may include staff and students
  - Must include a community member and a non-scientist (sometimes the same person)

The IRB Offices

- The IRBs are supported by the administrative staff of each IRB office.
- The IRB staff manages workflow and communications between IRB reviewers and investigators.
- Most investigator interaction is with the IRB staff rather than with the IRB members.

What is necessary for IRB approval?

1. Risks to subjects are minimized
2. Risks to subjects are reasonable in relation to anticipated benefits
3. Selection of subjects is equitable
4. Informed consent is sought (or waiver of consent is justified)
5. Informed consent is appropriately documented (or waiver of documented consent is justified)
6. Adequate plans to monitor data collection for safety of subjects
7. Adequate provisions to protect privacy and confidentiality
8. Additional safeguards to protect vulnerable populations (e.g. children, prisoners and etc.)

The IRB application MUST sufficiently describe these elements consistently in all responses and documents

IRB Review Paths

Full Board Review

- Any more than minimal risk research
- Most FDA regulated research (drugs/devices)
- Complex projects
- Review by a convened IRB (6-8 weeks (IRB-HSBS))

Expedited* Review

- Minimal risk research
- Meets certain federal criteria
- Reviewed by a **single** IRB member (2-4 weeks (IRB-HSBS))

** **Expedited** does not always mean fast!*

IRB Review Paths

Exempt Review

- Minimal risk research
- Meets certain federal criteria
- Reviewed by a **single** IRB member or staff member (1-2 weeks (IRB-HSBS))

Coming in July 2018 – Exempt determinations by investigators

Not Regulated

- Research involving de-identified data or biospecimens only
- QA/QI
- Oral histories/journalism

What complicates the IRB approval process?

- Inconsistent/incomplete/unclear IRB applications
  - Missing documents
  - Incomplete description of the research protocol
  - Poorly written consent documents
- Collaborative research
  - IRB approvals or IRB authorization agreements for collaborators research activities
  - New single IRB-of-Record requirements
- International research
  - In-country IRB/ethics review board or other approvals (e.g. Ministry of Health, Research Boards)
- Data use or materials transfer agreement process
- Other requirements - DoD HRPO review, Certificates of Confidentiality, etc.

Timing for Award and IRB Approval

- IRB approval typically not required at time of proposal submission
- Do not submit an IRB app until project receives “Just in Time” request
    - Could be wasteful of investigators’ and IRB’s time to review and approve a project that won’t be conducted without funding
- Umbrella approval
    - Delayed onset approval
    - May be appropriate in order to release funds for study development (usually 3-6 months of prep time)

sIRB

Requirement for use of a single IRB (sIRB) in multi-site research

- **NIH sponsored**
  - Effective January 25, 2018
  - Would apply to all NIH supported multi-site studies (domestic sites only)
  - Not limited to clinical research
- **Common Rule: When federally sponsored**
  - Planned effective date is January 20, 2020
  - Would apply to all federally supported multi-site studies
  - Not limited to clinical research

NIH sIRB

- Investigators must designate the single IRB-of-Record as part of the grant or contract application.
    - The single IRB-of-Record may be an external IRB:
        - Accredited commercial IRB
        - Other academic IRB
- When a U-M Principal Investigator (PI) is the awardee of a multi-site grant, U-M will evaluate whether it will act as the IRB-of-Record or cede IRB oversight to an external IRB *on a case-by-case basis*.

Contact the applicable U-M IRB **early** to discuss the sIRB options.

sIRB

When relying on a single IRB, only IRB regulatory oversight is ceded to the single IRB – many of the study team obligations remain in-house such as:

- All ancillary committee reviews
  - Research Pharmacy, Radiation Safety, etc.
- Conflict of Interest review and management plans
- Monitoring
- Maintaining compliance with educational requirements

Certificates of Confidentiality (CoC)

- CoCs are used to protect identifiable, sensitive research information or records from compelled disclosure.
- For NIH-funded research, as of October 1, 2017 (and retroactively applicable to active research projects as of December 13, 2016), all projects are issued a CoC as part of the terms and conditions of the research.
    - Must be sure that collaborators/subawardees are aware of these required protections
- Current application process still applies for non-NIH funded projects.

NIH CoC Kiosk:
https://humansubjects.nih.gov/coc/index

Where to get more information

- IRB-HSBS
  http://research-compliance.umich.edu/irb-health-sciences-and-behavioral-sciences-hsbs
- IRBMED
  https://research.medicine.umich.edu/office-research/institutional-review-boards-irbmed
- U-M IRB Contacts
  Contact info (e.g., http://research-compliance.umich.edu/u-m-irb-contacts)
- Pre-application Checklist
  http://umich.edu/~eresinfo/errm/start/preappchklist.html
- U-M Implementation: NIH Single IRB-of-Record (sIRB)
  http://research-compliance.umich.edu/human-subjects/common-rule-other-changes/u-m-implementation-nih-single-irb-record-sirb

Questions?

Thank you!

Professional Development Spotlight

Research Administrators' Network

February 22, 2018

David Mulder, Training Manager, ORSP / Sponsored Programs

National Council of University Research Administrators (NCURA) Update

Research Administrators' Network

February 22, 2018

NCURA Update

National Council of University Research Administrators (NCURA)

Upcoming Conferences:

- Financial Research Administration Annual Meeting – March 1-3, 2018 – Orlando, FL
- Pre-Award Research Administration Annual Meeting – March 3-5, 2018 – Orlando, FL
- Region IV Annual Meeting – April 15-18, 2018 – Des Moines, IA
- National Annual Meeting – August 5-8, 2018 – Washington, DC

Anyone interested in getting involved with NCURA should contact Region IV Volunteer Coordinator **Sue Grimes** at sgrimes@purdue.edu.

NCURA
Supporting Research...together™

National Organization of Research Development Professionals (NORDP) Update

Research Administrators' Network

February 22, 2018

NORDP Update

National Organization of Research Development Professionals (NORDP)

- The 10th Annual NORDP Research Development Conference will be held May 7-9, 2018, at the Hyatt Regency Crystal City in Arlington, VA.
- Visit http://www.nordp.org/annual-conference for more information.

Jill Jividen (Asst. Director for Research Development, Medical School) serves on the Member Services Committee for the Great Lakes Region of NORDP. Contact Jill (jjgoff@med.umich.edu) with any questions about NORDP.

NORDP
National Organization of Research Development Professionals

Society of Research Administrators International (SRAI) Update

Research Administrators' Network

February 22, 2018

SRAI Update

Society of Research Administrators International (SRAI)

- The SRAI Michigan Chapter Meeting will be held June 29, 2018, at the Central Michigan University in Mount Pleasant, MI.
- Visit https://srainternational.org/meeting/chapter/2018-michigan-chapter-meeting for more information, including a Call for Speakers

Ruth Halsey (Post-Award Financial Manager, Internal Medicine-Cardiology) serves as the President of the Michigan Chapter. Contact Ruth (halseyr@umich.edu) with any questions about SRAI.

SRA International
Society of Research Administrators International

Professional Societies Information

National Council of University Research Administrators (NCURA)

http://www.ncura.edu/

National Organization of Research Development Professionals (NORDP)

http://www.nordp.org/

Society of Research Administrators International (SRAI)

http://srainternational.org/

Navigate Update

Research Administrators' Network

David Mulder, Training Manager
February 22, 2018

Navigate Update

Navigate Professional Development Program

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Upcoming Classes:

- ***Fundamentals***: 7 Days, March 14 - June 7, 2018
- ***Uniform Guidance Cost Principles*** (2 Offerings):
  - 1 Day, March 13, 2018 - Ann Arbor Campus, OR
  - 1 Day, April 10, 2018 - Dearborn Campus

Application Deadline Extended to Tuesday, February 27, 2018!

Stay tuned to the RAP and RAPid for future class announcements, including Budgeting courses, and Lunch & Learn events.

For more info, visit orsp.umich.edu/navigate or email navigate-research@umich.edu.

Closing Remarks

- Thanks to the RAAC Communications Subcommittee!
- Ideas for a future meeting? **ran-plans@umich.edu**
- Next RAN meeting:
  - **May 15, 2018**
  - **2:00 – 3:30 pm** (followed by the UMOR Staff Recognition Awards)
  - **Michigan League Ballroom**